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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,636	04/01/2004	Patrick T. Petruno	10040213-1	1047

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EXAMINER

YU, MELANIE J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/816,636

Applicant(s)

PETRUNO ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed 16 May 2005 has been entered. Claims 2-12 and 21-29 are currently pending. Claims 1 and 13-20 have been canceled.

Election/Restrictions

In view of applicant's amendment filed 16 May 2005, a new restriction requirement has been issued.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 27-29 are drawn to a system comprising a first and second photodetector, classified in class 422, subclass 52.
- II. Claims 10-12 and 21-26 are drawn to a system comprising a first photodetector and medium in a single-use module, classified in class 422, subclass 68.1.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions of group I and II are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The system of group I requires a second photodetector, which is not required of the system of group II. The system of group II requires a first photodetector and medium contained in a single-use module, which is not required of the system of group I.
2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have

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acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Mr. David Millers on 25 July 2005 a provisional election was made with traverse to prosecute the invention of group II, claims 10-12 and 21-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-9 and 27-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

5. Claim 26 is objected to because of the following informalities: Claim 26 is qualified as an original claim, but is a new claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 10-12 and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, it is unclear whether the medium is intended to be part of the rapid diagnostic system. The claim merely recites the medium being illuminated by a light source, but does not recite the medium as part of the system. Furthermore, it is unclear whether the medium contains a sample, labeling substance, fluorescent structure

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and target analyte or whether the medium contains a sample and the sample further is comprised of a labeling substance, fluorescent structure and target analyte.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 10-12 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (US 5,837,546) in view of Straus (US 2003/0082516).

Regarding claims 10 and 23-25, Allen et al. teach a diagnostic system comprising: a light source for illuminating a medium containing a sample under test (light source, col. 9, lines 39-41; col. 13, lines 38-41) wherein the medium comprises a labeling substance (col. 12, lines 23-38) and a detector to measure a signal from a test area of the medium (col. 3, lines 15-21), wherein the detector and medium are contained in a single-use module (col. 12, line 49-col. 13, line 17). Allen et al. fail to teach a labeling substance that binds a persistent fluorescent structure to a target analyte and the detector being a photodetector.

Straus teaches a medium comprising a labeling substance that binds a quantum dot to a target analyte (quantum dot used as a fluorescent signal element for labeling a molecule, labeling molecules bound to cell, par. 69, 203-204) and a photodetector positioned to measure light (photodetectors used to measure properties, par. 169, 222) that has a frequency characteristic of fluorescent light resulting from the light source illuminating the quantum dot (quantum dots generate strong fluorescent signal therefore the photodetector detects light that has a frequency characteristic of fluorescent light, par. 203), in order to achieve high signal intensities.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the system of Allen et al., the medium comprising a labeling substance that binds a quantum dot to a target analyte and a photodetector to measure fluorescent light from the quantum dot as taught by Straus, in order to provide a label with a more stable and stronger signal.

With respect to claims 11 and 12, Allen et al. teach a reusable module having a receptacle into which the single-use module can be inserted for communication of test signals between the single-use module and the reusable module (single-use module, Fig. 6 and 7; reusable module outside casing, parts 62 and 64 shown in Fig. 4). Allen et al. teach the electronic components, such as the outside housing for display can be reused while the inside components are disposable, therefore the single-use module would be inserted into the reusable module for communication (col. 48-53). Furthermore, claim 12 recites the reusable module implementing a user interface, which is drawn to a method and does not appear to recite any further structural limitations, therefore a device must only be capable of performing the recited method. Since Allen et al. teach the required structural limitations, the reusable module of Allen et al. would be capable of implementing a user interface for indicating test results (housing of the photodetector and test strip 62 and 64, Fig. 4).

With respect to claims 21 and 22, Allen et al. teach a user interface comprising a display for test results (col. 3, lines 27-28) and electrical test signals (col. 3, lines 20-23 and 41-44)

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Regarding claim 26, Allen et al. teach a lateral flow strip for performing a binding assay (col. 11, lines 43-49), and the test area contains an immobilized substance that binds to and holds a complex including the labeling substance and the target analyte (par. 11, lines 43-48).

Response to Arguments

2. Applicant's arguments, see pages 5-6, filed 16 May 2005, with respect to the rejection(s) of claim(s) 1-12 under 35 USC 102(e) and 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a further search of currently amended claim 10 and new claims 21-26.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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07/27/05